Supreme Court, U.S.
FILED

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No. 03 557 OCT 10 2003

IN THE

Supreme Court of the United States

ST. LOUIS UNIVERSITY, a corporation,

Petitioner,

—v.—

AMERICAN CYANAMID COMPANY,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

1. In light of *Berkovitz v. United States*, 486 U.S. 531 (1988), and the decisions of the Third, Fourth, Eighth, and Ninth Circuits, is it sufficient to hold a manufacturer liable for oral polio vaccine ("OPV") injuries upon a showing that (1) the federal safety regulations were violated, (2) the non-compliant vaccine caused the disease, and (3) but for the release and marketing of the non-compliant vaccine no OPV injury was possible?

PARTIES IN THE PROCEEDING BELOW

1. St. Louis University ("SLU"), a corporation, Petitioner;

2. American Cyanamid Company ("Cyanamid"), a corporation;

3. United States Government.*

CORPORATE DISCLOSURE STATEMENT

St. Louis University makes this corporate disclosure statement pursuant to Supreme Court Rule 29.6:

1. St. Louis University has no parent corporation.

2. No publicly-held corporation owns 10 percent or more of the stock of St. Louis University.

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* Although the Fourth Circuit decision giving rise to this Petition did not involve the Government as a party, the Government was involved in the District Court proceeding out of which the Fourth Circuit decision arose. *See* CITATIONS OF OPINION AND ORDERS IN CASE, *infra*.

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* To be consistent with the citation of these federal regulations by the District Court below ever since it presided over the multi-district *Sabin* OPVcases, Petitioner will cite to these OPV regulations by their original number, even though they were later renumbered in 21 C.F.R. §§ 630.10-630.17. *See In re Sabin Oral Polio Vaccine Products Liability Litigation*, 763 F. Supp. 811, 813 n.2 (D. Md. 1991) ("*Sabin II*") ("I will cite to them (as I did in my earlier opinion) by their original number").

CITATIONS OF OPINIONS AND ORDERS IN CASE

The decision giving rise to this Petition was issued by the United States Court of Appeals for the Fourth Circuit: *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003). The opinion is attached as Appendix A. (A companion decision, *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003), was also issued by the Fourth Circuit, and is attached as Appendix B for the Court's convenience.[1])

The United States District Court for the District of Maryland was the trial court in this matter, and addressed in a single opinion the claims of St. Louis University against both Cyanamid, the vaccine manufacturer, and the United States Government, which tested and approved the vaccine. Upon appeal, the Fourth Circuit split the matter apart and issued the two individual decisions cited above. It affirmed the District Court's grant of summary judgment in favor of American Cyanamid against SLU, and it reversed the District Court's grant of summary judgment in favor of SLU against the Government, remanding for entry of judgment in favor of the Government.

The District Court opinion and order that gave rise to both appellate decisions, *St. Louis University v. United States*, 182 F. Supp. 2d 494 (D. Md. 2002), is attached as Appendix C.

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[1] Petitioner is submitting a separate Petition for Certiorari regarding *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003). At the appellate level, SLU petitioned for rehearing *en banc* in that matter, a petition denied by the Fourth Circuit on Aug. 12, 2003. Accordingly, that Petition for Certiorari, which involves the distinct issue of Government liability, will be submitted to this Court within 90 days of August 12, 2003.

JURISDICTIONAL STATEMENT

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1). The Fourth Circuit's judgment was entered July 16, 2003. The instant Petition is filed with 90 days of that decision, pursuant to Supreme Court Rule 13.

FEDERAL REGULATIONS INVOLVED

This case involves a contribution claim made by St. Louis University against the US Government and American Cyanamid. SLU was sued by Danny Callahan for administering to him a defective vaccine, a vaccine that gave him polio. Callahan was awarded $16 million in his suit. Because the vaccine was negligently manufactured and distributed by American Cyanamid, SLU sought contribution from Cyanamid.

The regulations at issue specify the mandatory safety requirements that govern the manufacture and sale of polio vaccines. Cyanamid violated all of the safety regulations, 42 C.F.R. § 73.110 *et seq.*, in its manufacture and sale of its Orimune oral polio vaccine ("OPV").[2]

STATEMENT OF THE CASE

The Supreme Court should grant certiorari to resolve an issue which will promote the integrity of the federal

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[2] Petitioner had difficulty converting a copy of the 42 C.F.R. § 73.110 *et seq.* original regulations (which are from 1961) into a legible 6 by 9 inch typographic format and thus could not include them in the Petition Appendix. Accordingly, should the Court request a copy of those regulations, Petitioner will file an 8.5 by 11 inch copy with the Court. If that is insufficient, Petitioner will of course do whatever the Court otherwise directs.

regulatory process and promote uniformity of decisions among the Circuit courts.

The Fourth Circuit's decision has undermined the effective reach and purpose of the federal OPV regulations whose express purpose was to insure safe vaccines for all Americans. The Fourth Circuit interpreted Missouri law as holding plaintiff to a causation standard which insulates manufacturers from liability and negates the force and purpose of the federal vaccine regulations. Second, the Fourth Circuit's decision is in conflict with its previous decisions and those of other Circuits, which analyzed virtually identical facts under identical tort regimes with respect to the same regulatory framework.

The gravamen of the case is as follows. Cyanamid manufactured a polio vaccine that violated federal safety regulations in that it was excessively neurovirulent. The manufacturers also represented that the vaccine did in fact meet the regulations when it knew those claims were false. The Fourth Circuit's decision granting Cyanamid summary judgment requires that, to establish liability, petitioner must prove that the OPV victim would not have contracted polio from a compliant vaccine. That is an impossible liability requirement. Petitioner has proved excessive neurovirulence was the cause of the injury.

The Fourth Circuit's proximate cause analysis destroys the purpose of the safety regulations. It concluded that "SLU has simply failed to present any competent evidence showing that the defect in the vaccine—excessive neurovirulence—proximately caused SLU's injuries." *Cyanamid*, 336 F.3d at 310. The Fourth Circuit's reasoning was that were the regulations followed, Danny might have gotten polio anyway, owing to the inherent risk of polio even compliant live vaccines pose. *Id.* In short, because plaintiff did not prove Danny got polio

because of the *additional* risk posed to him by a non-compliant vaccine, the Fourth Circuit held that SLU did not satisfy causation.

First, there is no evidence that any live polio vaccine would have been able to satisfy the regulations during the applicable time period. Accordingly, had the regulations been followed, the only vaccine available to Danny would have been the inactive Salk vaccine, which presents *no polio risk*. As a matter of logic, the evidence presented by plaintiff—that the live vaccine was excessively neurovirulent and that its label not only failed to warn doctors that the vaccine was not in compliance with the applicable regulations, but falsely claimed compliance—proves proximate cause. No doctor would prescribe to his patient an excessively neurovirulent live vaccine that did not meet government regulations when a perfectly safe inactive vaccine was available.

Moreover, even assuming that some compliant version of a live polio vaccine could have made it to market, no proximate cause standard could require that Danny prove he got polio because of the *additional* risk. That is an impossible standard to meet. Contrary to the Fourth Circuit's view, neither Missouri nor any state's law defeats the claim.

The Court should grant certiorari.

SUMMARY OF FACTS

SLU paid a $ 16 million Missouri state-court judgment to the family of Danny Callahan, who contracted paralytic poliomyelitis after ingesting the Orimune polio vaccine. *St. Louis University v. United States*, 182 F. Supp.2d, 496-98 (D. Md. 2002); *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003); *American Cyanamid v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003). Approximately one month after receiving the

dose of Orimune, Danny developed a fever and perirectal abscesses. *St. Louis University v. United States*, 182 F. Supp.2d at 496-98. He was treated at Cardinal Glennon Hospital by SLU employees. *Id.* That judgment paid by SLU arose from SLU employee's actions in treating 3-month old Danny Callahan. *Id.* Although the abscesses improved, Danny's legs and left arm were permanently paralyzed. *Id.* The polio virus was isolated in Danny's stool, and doctors (and the District Court) concluded that Danny contracted paralytic poliomyelitis from the Orimune vaccine of live polio Type III. *Id:*

SLU subsequently asserted Cyanamid proximately caused Danny's paralytic poliomyelitis by manufacturing and marketing the excessively neurovirulent Orimune polio vaccine in violation of the applicable OPV neurovirulence regulations. *Cyanamid*, 336 F.3d. at 309. SLU also asserted the Government proximately caused Danny's polio by improperly approving and licensing the vaccine in violation of the applicable regulations. *United States v. St. Louis University*, 336 F.3d at 298.

THE DISTRICT COURT DECISION

The District Court opinion, *St. Louis University v. United States*, 182 F. Supp.2d 494 (D. Md. 2002), adjudicated both SLU's claims against the Government and against Cyanamid. To be properly understood the District Court's analysis of the claims against Cyanamid should be evaluated in contrast to its analysis of the claims against the Government. Accordingly, a brief review of the District Court's Government analysis follows.

Judge Frederick Motz of the District Court found that by releasing the Orimune vaccine lots the "United States is liable in contribution because its violations of its own regulations constituted negligence and were a proximate

cause of Callahan's paralysis." *St. Louis University v. United States*, 182 F. Supp.2d at 500. In making that determination, the District Court concluded "if the government had not wrongfully approved the seed from which the vaccine was derived, Callahan would never have been administered a dose of Orimune and would never had contracted polio" because the excessively neurovirulent vaccine given to Danny would never have been released at all. *Id.* at 499. The District Court further explained that "the neurovirulence criteria of the OPV regulations—which the government itself had adopted—provided the 'best available scientific standard' for determining excessive neurovirulence and that the government had therefore increased the risk of harm to the public." *Id.* at 502 (citing *In re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 774 F.Supp. 952 (D. Md. 1991) ("*Sabin III*") at 955). This was an echo of the District Court's conclusions in *Sabin III*, where Judge Motz found that because "neurovirulence test results exceeded the regulatory criteria, [the Government] increased the risk of harm to persons who were vaccinated. . .". *Sabin III*, 774 F.Supp. at 955.

After holding the Government liable, the District Court, in what it admitted was a seemingly "asymmetrical, paradoxical, or even perverse" holding, absolved Cyanamid from liability. *St. Louis University v. United States*, 182 F. Supp.2d at 500. This is especially puzzling because the District Court had before it not only the testimony of the regulators from the *In Re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 763 F.Supp 811 (D. Md. 1991) ("*Sabin II*") case, it had American Cyanamid's own documents which detailed the entire history of these violations and were authored by the key principals of the company during the period of 1962 through the 1980s. The upshot of the documents is that Cyanamid knew it was violating the regulations but, nevertheless, decided to turn a blind eye to

these results. "A final meeting was held December 21. According to a Lederle memorandum, all the participants agreed 'that [Lederle's] type 3 is more neurovirulent than type 1 reference.' " *Sabin II*, 763 F.Supp. at 820-821.[3]

The basis of the District Court's decision to absolve Cyanamid was Judge Motz's erroneous conclusion that the causation standard that applied to Cyanamid was somehow different than one that applied to the Government:

> [I]n analyzing the element of proximate cause in claims against Cyanamid, the focus must be on whether the plaintiff can prove that it was a defect in the OPV that resulted in his injury, not simply—as in a case against the Government—whether he had been exposed to OPV derived from a seed that had been improperly approved in violation of the regulatory process.

St. Louis University v. United States, 182 F. Supp.2d at 500.

Thereby, the District Court contradictorily concluded —in contrast to remarks it made about Orimune in the Government context—that with respect to the Cyanamid causation inquiry Orimune was not "excessively neurovirulent when administered to humans or that an OPV meeting the regulatory criteria would not have equally caused the Sabin III plaintiffs to contract polio." *Id.* at 502.

In so concluding, the District Court produced a surreal decision: one where, on the same facts, improperly approving the licensing of OPV caused Danny's triplegia, but improperly manufacturing the same OPV and asking for approval for licensing did not.

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[3] Lederle is a division of American Cyanamid.

THE FOURTH CIRCUIT APPELLATE DECISIONS

The District Court decision, holding the Government liable and absolving Cyanamid, was appealed, respectively, by the Government and by SLU. After entertaining those appeals, the Fourth Circuit issued two separate decisions, one involving Cyanamid, *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003) and one involving the Government, *United States v. St. Louis University*, 336 F.3d 294 (4th Cir. 2003). Because the Government decision was referred to by the Fourth Circuit in the Cyanamid opinion, the latter is summarized here for the Court's convenience. In sum, the Fourth Circuit's Government decision overturned the District Court finding of liability against the Government, notwithstanding the factual findings that (1) the Government released the excessively neurovirulent Orimune vaccine in violation of the mandatory federal OPV neurovirulence regulations;[4] (2) this excessively neurovirulent Orimune vaccine was received by three-month old Danny Callahan;[5] (3) this Orimune vaccine whose excessive "ability to cause paralytic poliomyelitis"[6] violated the OPV regulations did in fact cause

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[4] *United States v. St. Louis University,* 336 F.3d at 298 (accepting district court's finding that "the vaccine seeds from which the [Orimune] lots were derived did not meet the neurovirulence standards set forth in the governing regulations").

[5] *United States v. St. Louis University,* 336 F.3d at 298 ("The Orimune vaccine received by Danny Callahan was derived from one of the vaccine seeds that the district court in the *Sabin* cases concluded were improperly approved by the government.").

[6] *Berkovitz v. United States*, 486 U.S. 531, 544 n.9 (1988) (Supreme Court defining "neurovirulence")

paralytic poliomyelitis in Danny;[7] and (4) had the Government not violated its own federal OPV regulations, the excessively neurovirulent Orimune vaccine which Danny received would never have been released at all.[8]

The Fourth Circuit's reasoning was the "proximate cause" had not been established against the Government: "we conclude that SLU was required to establish that Danny likely would not have contracted polio . . . from a vaccine that satisfied the government's neurovirulence standards." *United States v. St. Louis University,* 336 F.3d at 302.

In the companion Cyanamid appellate decision, the Fourth Circuit affirmed the District Court's grant of summary judgment, using identical proximate cause reasoning as in the Government appeal: "SLU presented no expert testimony showing that Danny Callahan would not have contracted polio . . . had he been given a vaccine complying with the regulations." *Cyanamid*, 336 F.3d at 309.

There are two obvious problems with the above "proximate cause" reasoning. First—just as the District Court concluded with respect to the Government's improper approval of the product—had Cyanamid actually complied with the regulations, Orimune would never have

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[7] *United States v. St. Louis University,* 336 F.3d at 297 ("doctors ultimately concluded that Danny suffered from vaccine-associated polio").

[8] *United States v. St. Louis University,* 336 F.3d at 298 (accepting district court's finding that Government "violat[ed] its own regulatory standards [by] approving for release vaccine derived from seeds that exceeded the neurovirulence standards"); *see also, id.* at 306 (Luttig, J., dissenting)(explaining that had the Government complied with the OPV regulations, "none of the offending vaccine would have been distributed at all").

reached Danny's lips. It was simply impossible for the defective vaccine to have been manufactured and distributed if the regulations were complied with. Thus, were the regulations followed, Danny would have been inoculated with an alternative vaccine: the Salk vaccine. Importantly, the Salk vaccine cannot cause polio; it is 100% safe. Put another way, if either the Government or Cyanamid had followed the regulations, Danny could not have gotten polio.

Second, the proximate cause standard adopted by the Fourth Circuit requires a showing that, in the words of the District Court, is logically "unknowable and unprovable." *St. Louis University v. United States*, 182 F. Supp.2d at 502 ("Whether or not an oral polio vaccine that complied with the OPV regulations would have caused Callahan and the plaintiffs in the other Sabin cases to contract polio ultimately is unknowable and unprovable"). Namely, the Fourth Circuit required plaintiff to show that Danny would *not* have gotten polio had he taken a hypothetically compliant live vaccine. Of course, since even a hypothetically compliant live vaccine (unlike the Salk vaccine) has an inherent risk of polio, the Fourth Circuit well knew that there could never be such evidence to prove its invented standard. The Fourth Circuit's causation burden is akin to requiring one cheated by a loaded die to prove that a fair die couldn't have also resulted in a losing outcome. That is asking the impossible.

By forcing that impossible proximate cause standard on plaintiff, the Fourth Circuit deliberately ensured that the manufacturer will always escape liability for violating the mandatory federal safety regulations which are enacted to protect the innocent children who are required to be immunized for their good and the public good. Accordingly, the decision conflicts with the precedent of

the Supreme Court, Third Circuit, Fourth Circuit (in the previously decided *In Re Sabin Oral Polio Vaccine Prod. Liab. Litig.*, 984 F.2d 124 (4th Cir. 1993) ("*Sabin IV*"), Eighth Circuit, and Ninth Circuit, which all subjected a product approver, the Government, to liability for releasing non-complaint vaccine in violation of mandatory federal OPV regulations. The fact that the cases referred to herein involve the Government in a product approver capacity rather than a manufacturer does not eliminate the existence of conflict. Rather, it makes the conflict more stark: other Circuits subjected the *product approver* (the government) to liability for a defective vaccine Only by fabricating an impossible causation standard could the Fourth Circuit absolve the actual *product manufacturer*—a party much closer to the victim in the chain of liability—of liability for the same defective vaccine. It is simply unjust that a tortfeasor who fails to obey a single regulatory command, who failed to perform the tests properly, and who failed to submit the data to the Government would escape liability.

This Court should now grant certiorari to resolve this conflict.

EXISTENCE OF JURISDICTION IN COURTS BELOW

This contribution action was commenced in the United States District Court for the District of Maryland. The District Court had jurisdiction over the matter pursuant to the 28 U.S.C. §1331 and 1332.

The District Court granted summary judgment against the Government and in favor of Cyanamid on January 25, 2002. *St. Louis University v. United States*, 182 F. Supp.2d 494 (D. Md. 2002). The District Court certified the order as appropriate for immediate review, and the United States

Court of Appeals for the Fourth Circuit granted the Government and SLU permission to bring interlocutory appeal under 28 U.S.C. § 1292(b). On July 16, 2003, the Fourth Circuit affirmed the District Court's grant of summary judgment in favor of Cyanamid. *American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003).[9]

ARGUMENT FOR ALLOWANCE OF THE WRIT

By rejecting the binding precedent of the Supreme Court in *Berkovitz v. United States*, 486 U.S. 531 (1988) and the Fourth Circuit in *Sabin IV,* and thereby disregarding the fundamental doctrine of *stare decisis*, the Fourth Circuit has radically departed from traditional federal practice. *See* Sup. Ct. R. 10(a) (review on certiorari warranted where decision "so far departed from the accepted and usual course of judicial proceeding . . . as to call for an exercise of this Court's supervisory power").

Moreover, by shielding Cyanamid from liability for violating federal vaccine regulations in manufacturing and marketing a noncompliant vaccine, the Fourth Circuit decision below necessarily conflicts with the logical extension of precedents of the Third,[10] Eighth[11] and Ninth Circuits,[12] all of which subjected a mere product-approver to liability for violating analogous mandatory federal regulations. By force of logic and common-

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[9] The same day, the Fourth Circuit reversed the District Court's grant of partial summary judgment in favor of SLU, and directed entry of final judgment in favor of the Government. *United States v. St. Louis University,* 336 F.3d 294 (4th Cir. 2003).

[10] *Griffin v. United States*, 500 F.2d 1059 (3rd Cir. 1974).

[11] *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981).

[12] *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987).

sense, if those merely approving the product are subject to liability, the same must also be true of those manufacturing the product. Thus the conflict presents itself: where in several circuits those approving the product are subject to liability, in the Fourth Circuit the party *actually manufacturing* the product is shielded. *See* Sup. Ct. R. 10(a) (review on certiorari warranted where "a United States court of appeals has entered a decision in conflict with the decision of another United States court of appeals on the same important matter"). That simply cannot be right.

This Court should now grant certiorari to review and reverse the Fourth Circuit decision. By holding Cyanamid, the defective product manufacturer, liable for violating mandatory federal vaccine safety regulations, the Supreme Court would restore uniformity to the federal vaccine regulations and uphold public confidence in the regulatory system and the rule of law itself.

I. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Disregarded The Binding United States Supreme Court Precedent Of *Berkovitz* That Subjected a Product Approver To Liability For Violating Federal OPV Safety Regulations.

In *Berkovitz v. United States*, 486 U.S. 531 (1988), the Government was sued under the FTCA for releasing the excessively neurovirulent Orimune vaccine in violation of the federal OPV safety regulations. The Government sought to escape liability under the FTCA's discretionary function exception. The *Berkovitz* Court rejected the discretionary function doctrine as inapplicable, paving the way for a product-approver to be subject to liability. In so doing, the Court noted the heightened duty product manufacturers bore, above and beyond the duty of the

Government: "[the] regulations place[ ] an obligation on manufacturers to examine all vaccine lots prior to distribution to ensure that they comply with regulatory standards. . . . These regulations, however, do not impose a corresponding duty" on the Government. *Berkovitz*, 486 U.S. at 545-546. The implication of *Berkovitz* was clear: if the Government, the party with the *lesser* obligation, is subject to liability for violating the regulations, then so too must be the manufacturer.

In the instant case, Cyanamid violated the federal OPV regulations by producing and distributing the noncompliant vaccine that paralyzed Danny. Importantly, violating the regulations has a clear physical consequence: it "increased the risk that several more individuals would contract polio as a result of exposure to OPV than would have done if the OPV regulations had been strictly followed." *St. Louis University v. United States*, 182 F. Supp.2d at 503. The fact that such remarks were made in the context of the Government violating regulations does not undo their force: Cyanamid's violations in manufacturing the vaccine increased the risk of contracting polio just as much as did the Government's violations in approving the vaccine.

By shielding Cyanamid from liability in case wherein Cyanamid exposed product users to a defective product that increased the risk of polio, the Fourth Circuit has rejected binding Supreme Court *Berkovitz* precedent that subjects product-approvers, and by necessary extension product manufacturers, to liability for violating OPV safety regulations that prohibit the distribution of an excessively neurovirulent vaccine. Accordingly, this Court should now grant certiorari to correct the Fourth Circuit for "so depart[ing] from the accepted and usual course of judicial proceedings" in rendering the below decision in disregard of binding Supreme Court prece-

dent, *stare decisis*, and the proper order of our federal judicial system. Sup. Ct. R. 10(a).

II. In A Radical Departure From Traditional Federal Practice That Warrants Correction By The Supreme Court, The Fourth Circuit Panel Disregarded The Binding Fourth Circuit Precedent Of *Sabin IV* That Subjected a Product-Approver to Liability For Violating Federal OPV Safety Regulations.

In addition to improperly rejecting the binding Supreme Court precedent of *Berkovitz*, the Fourth Circuit flouts the fundamental doctrine of *stare decisis* by rejecting the binding Fourth Circuit precedent of *Sabin IV*. *See Sabin IV*, 984 F.2d at 128 (4th Cir. 1993) (holding product *approver* did proximately cause and was liable for plaintiffs' paralytic poliomyelitis by releasing Orimune in violation of mandatory federal neurovirulence regulations); *compare American Cyanamid Company v. St. Louis University*, 336 F.3d 307 (4th Cir. 2003) (holding product *manufacturer* did *not* proximately cause and was not liable for plaintiff's paralytic poliomyelitis by releasing Orimune in violation of mandatory federal neurovirulence regulations).

Sabin IV explicitly held that the causal connection between plaintiff's injuries and violation of the OPV regulations was "logical, sensible and direct." *Sabin IV*, 984 F.2d at 128 (affirming district court's conclusion of same). The fact that *Sabin IV* involved the Government's violations, and not Cyanamid's, does not mean the its reasoning is not binding. Causation is causation. Specifically, proximate cause is the same whether applied to a product approver or a product manufacturer, a truism the Fourth Circuit panel admitted, explaining that the approver/manufacturer distinction "has no effect on the general

rules of causation." *United States v. St. Louis University*, 336 F.3d at 302. Thus the below decision had no legal or factual basis on which to reach the conclusion it reaches, other than it is unhappy with the reasoning *Sabin IV*.[13]

However, in a transparent effort to ignore binding proximate cause reasoning issued under an identical tort regime in *Sabin IV*, the Fourth Circuit panel seized upon an imaginary distinction. It claimed Missouri law to be different than the Florida and Maryland law governing *Sabin IV*, which amounted to a sophisticated excuse from having to follow the precedent in *Sabin IV*. Yet in its vigor to demonstrate this alleged difference, the panel contorted Missouri proximate cause law into absurdity. It demanded of SLU a showing that "Danny Callahan would not have contracted polio or would have contracted a less severe case had he been given a vaccine complying with the regulations." *Cyanamid*, 336 F.3d at 310. Of course, Missouri law requires no such impossible proof of causation. Nor does the law of any state. All that is required, as in *Sabin IV*, is that the defect was a substantial factor in bringing about a reasonably related harm.[14]

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[13] Petitioner is not suggesting the Fourth Circuit can never reverse course. However, because the below proceeding occurred before a *panel*, the panel does not have the authority to ignore or overturn binding precedent. Only the Fourth Circuit *en banc*, or this Court, can do that. *See St. Louis University v. United States*, 336 F.3d at 305 (panel "is bound to abide . . . until [the Fourth Circuit] *en banc* or the Supreme Court holds otherwise") (Luttig, J., dissenting). To do otherwise is to violate *stare decisis*.

[14] Missouri law adopts the standard of Restatement (Second) of Torts § 431 (conduct is proximate cause of injury if it "is a substantial factor in bringing about the harm"). S*ee Todd v. Watson*, 501 S.W.2d 48, 52 (Mo. 1973) (citing Rest. (2d) Torts § 431: "To be a legal cause of harm to another, one's conduct must be a substantial factor in brining about the harm"); *see also Robinson v. Missouri State*

Thereby, by flouting the fundamental principle of *stare decisis* in its rejection of the binding principle of *Sabin IV*, the Fourth Circuit panel "so far departed from the accepted and usual course of judicial proceedings" as to warrant review and reversal by the Supreme Court on certiorari. Sup. Ct. R. 10(a).

III. The Fourth Circuit's Decision Shielding Cyanamid From Liability Conflicts With Third, Eighth, and Ninth Circuit Precedent Subjecting a Product Approver To Liability For Violating Federal OPV Safety Regulations, And Thereby Destroys Uniformity In The Federal OPV Regulations.

The decisions of sister Circuits illuminate the Fourth Circuit's radical and unwarranted break from the liability scheme the federal OPV regulations contemplate.

The Third Circuit, in *Griffin v. United States*, 500 F.2d 1059 (3rd Cir. 1974), affirmed a finding of liability against the Government and held that the proximate cause standard against a product approver was satisfied under conditions functionally identical to the instant case. In analyzing the issue of causation, the Third Circuit affirmed the district court's finding of proximate cause, concluding that proximate cause was satisfied because (a) plaintiff developed Type III polio from a vaccine, as did Danny, and that (b) plaintiff ingested a

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Highway & Transp. Comm'n, 24 S.W.3d 67, 78 (Mo. Ct. App. 2000) (per curiam) (proximate cause test is whether "the injury appears to be the reasonable and probable consequence of the act or omission of the defendant . . . . It is only necessary that the party charged knew or should have known there was an appreciable chance some injury would result") (internal citations omitted). Here, by manufacturing the excessively neurovirulent vaccine in violation of the regulations and falsely claiming compliance with same, Cyanamid created an appreciable chance that one exposed to the defective vaccine would contract polio.

noncompliant vaccine, as did Danny. *Griffin,* F.2d 1059 at 1070.

The Eighth Circuit in *Loge v. United* States, 662 F.2d 1268 (8th Cir. 1981), held the FTCA discretionary function exception did not shield the Government for violating the mandatory federal OPV regulations. *Id.* at 1272-74. The Court further explained that:

> [T]he Government increased the risk of harm to the Loges by licensing an allegedly untested product, Orimune, and by releasing to the public an allegedly untested or negligently tested lot of that vaccine: if either the product itself or a particular lot of that product failed to conform to the standards established by the regulations, then proper testing or proof of testing would have revealed the nonconformity and the vaccine would never have been disseminated to Todd Loge.

Loge, 662 F.2d at 1274. Accordingly, the Eighth Circuit deemed a product approver subject to liability wherein it (a) violated applicable regulations and (b) increased the risk of harm to those taking the vaccine. *Id.* at 1274-1275. Both are true of the product manufacturer here.

The Ninth Circuit, in *Baker v. United* States, 817 F. 2d 560 (9th Cir. 1987), held that product approvers could not violate mandatory OPV safety regulations "that serve to protect susceptible persons from contracting the [polio] disease." *Id.* at 561. Ultimately, *Baker* concluded that the product approver "may be subjected to tort liability for the alleged negligence of an agency employee in failing to follow a specific mandatory [OPV] regulation." *Id.* at 563-65. It specifically noted that "[a]gency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data." *Id.* at 566. Clearly the Eighth Circuit does not

believe that the manufacturer, who submits said data, is to be shielded from liability.

In vivid contrast to the foregoing decisions, the Fourth Circuit categorically absolved a product manufacturer from liability, imposing an unprovable proximate cause standard. The Fourth Circuit did so even though Cyanamid manufactured and marketed a product that failed to comply to the applicable regulations—regulations which the Supreme Court explained were more onerous than the safety regulations binding the Government. *Berkovitz*, 486 U.S. at 545-546. Therefore, the below Fourth Circuit decision to shield a product manufacturer from liability for violating regulations governing the manufacture and release of the Orimune vaccine conflicts with Third, Eighth, and Ninth Circuit decisions that refused to shield a product approver from liability for violating regulations governing the manufacture and release of the Orimune vaccine. Accordingly, this Court should now grant certiorari to resolve this conflict. *See* Sup. Ct. R. 10(a), *supra.*

CONCLUSION

For the reasons set forth above, this Petition for Writ of Certiorari should be granted.

Respectfully submitted,

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